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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, **Plaintiff,** **v.** **NATCO PHARMA LIMITED,** **Defendant.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Celgene Corporation ("Celgene"), by its undersigned attorneys, for its Complaint against defendant Natco Pharma Limited ("Natco" or "Defendant"), alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Natco's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Celgene's REVLIMID® drug product prior to the expiration of United States Patent Nos. 5,635,517 (the "'517 patent"), 6,045,501 (the "'501 patent"), 6,281,230 (the "'230 patent"), 6,315,720 (the "'720 patent"), 6,555,554 (the "'554 patent"), 6,561,976 (the "'976 patent"), 6,561,977 (the "'977 patent"), 6,755,784 (the

"'784 patent"), 7,119,106 (the "'106 patent"), and 7,465,800 (the "'800 patent") owned by Celgene (collectively, "the patents-in-suit").

The Parties

2. Plaintiff Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. On information and belief, defendant Natco is a corporation organized and existing under the laws of India, having a principal place of business at Natco House, Road No. 2, Banjara Hills, Hyderabad 500 033 India.

4. On information and belief, Natco is registered to do business in the State of New Jersey. On information and belief, Natco also regularly transacts business within this judicial district. Further, on information and belief, Natco develops numerous generic drugs for sale and use throughout the United States, including in this judicial district. On information and belief, Natco also prepares and/or aids in the preparation and submission of ANDAs to the FDA. Additionally, on information and belief, Natco has partnered with an unknown generic pharmaceutical company based in the United States ("Natco's Unknown Partner") to market and distribute Natco's generic drug products complained of herein, including in this district. On information and belief, Natco's Unknown Partner regularly conducts business in this judicial district, including marketing and selling pharmaceutical products. Prior to filing suit, Celgene asked counsel for Natco to identify Natco's Unknown Partner. Natco's counsel refused, but did not deny that such partner exists.

Jurisdiction and Venue

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Natco by virtue of, *inter alia,* its systematic and continuous contacts with the State of New Jersey. On information and belief, Natco has purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. On information and belief, Natco also has purchased retail pharmacies in the State of New Jersey. Further, on information and belief, Natco has customers in the State of New Jersey. Additionally, on information and belief, Natco's Unknown Partner makes, ships, uses, offers to sell or sells, or causes others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and derives revenue from such activities. On information and belief, Natco's Unknown Partner also has customers in the State of New Jersey.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patents in Suit

8. On June 3, 1997, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '517 patent, entitled "Method of Reducing TNFα Levels with Amino Substituted 2-(2,6-dioxopiperidin-3-yl)-1-oxo-and 1,3-dioxoisoindolines" to Celgene as assignee of the inventors George W. Muller, David I. Stirling, and Roger Shen-Chu Chen. On June 29, 1999, the USPTO duly and lawfully issued a reexamination certificate for the '517 patent. On March 27, 2008, the USPTO extended the term of the '517 patent under 35 U.S.C. § 156 for a period of 1,167 days. A copy of the '517 patent and its reexamination certificate are attached hereto as Exhibit A.

9. On April 4, 2000, the USPTO duly and lawfully issued the '501 patent, entitled "Methods for Delivering a Drug to a Patient While Preventing the Exposure of a Foetus or

Other Contraindicated Individual to the Drug" to Celgene as assignee of the inventors Marc Elsayed and Bruce Williams. A copy of the '501 patent is attached hereto as Exhibit B.

10. On August 28, 2001, the USPTO duly and lawfully issued the '230 patent, entitled "Isoindolines, Method of Use, and Pharmaceutical Compositions" to Celgene as assignee of the inventors George W. Muller, David I. Stirling, and Roger Shen-Chu Chen. A copy of the '230 patent is attached hereto as Exhibit C.

11. On November 13, 2001, the USPTO duly and lawfully issued the '720 patent, entitled "Methods for Delivering a Drug to a Patient While Avoiding the Occurrence of an Adverse Side Effect Known or Suspected of Being Caused by the Drug" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the '720 patent is attached hereto as Exhibit D.

12. On April 29, 2003, the USPTO duly and lawfully issued the '554 patent, entitled "Isoindolines, Method of Use, and Pharmaceutical Compositions" to Celgene as assignee of the inventors George W. Muller, David I. Stirling, and Roger Shen-Chu Chen. A copy of the '554 patent is attached hereto as Exhibit E.

13. On May 13, 2003, the USPTO duly and lawfully issued the '976 patent, entitled "Methods for Delivering a Drug to a Patient While Preventing the Exposure of a Foetus or Other Contraindicated Individual to the Drug" to Celgene as assignee of the inventors Marc Elsayed and Bruce Williams. A copy of the '976 patent is attached hereto as Exhibit F.

14. On May 13, 2003, the USPTO duly and lawfully issued the '977 patent, entitled "Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the '977 patent is attached hereto as Exhibit G.

15. On June 29, 2004, the USPTO duly and lawfully issued the '784 patent, entitled "Methods for Delivering a Drug to a Patient While Restricting Access to the Drug by Patients for Whom the Drug May be Contraindicated" to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. On May 3, 2005, a certificate of correction was granted by the USPTO to correct a typographical error in claim 29 of the '784 patent. A copy of the '784 patent and its certificate of correction are attached hereto as Exhibit H.

16. On October 10, 2006, the USPTO duly and lawfully issued the '106 patent, entitled "Pharmaceutical Compositions of 1-oxo-2-(2,6-dioxopiperidin-3-yl)-4-aminoisoindoline" to Celgene as assignee of the inventors George W. Muller, David I. Stirling, and Roger Shen-Chu Chen. A copy of the '106 patent is attached hereto as Exhibit I.

17. On December 16, 2008, the USPTO duly and lawfully issued the '800 patent, entitled "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione" to Celgene as assignee of the inventors Markian S. Jaworsky, Roger Shen-Chu Chen and George W. Muller. A copy of the '800 patent is attached hereto as Exhibit J.

The REVLIMID® Drug Product

18. Celgene holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for lenalidomide capsules (NDA No. 21-880), which it sells under the trade name REVLIMID®. The claims of the patents-in-suit cover, *inter alia*, lenalidomide, solid forms of lenalidomide, pharmaceutical compositions containing lenalidomide, and methods of use and administration of lenalidomide or pharmaceutical compositions containing lenalidomide.

19. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to REVLIMID®.

Acts Giving Rise to this Suit

20. Pursuant to Section 505 of the FFDCA, Natco filed ANDA No. 201-452 ("Natco's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of lenalidomide capsules 5 mg, 10 mg, 15 mg and 25 mg ("Natco's Proposed Products"), before the patents-in-suit expire.

21. In connection with the filing of its ANDA as described in the preceding paragraph, Natco has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Natco's ANDA.

22. No earlier than August 30, 2010, Natco sent written notice of its ANDA certification to Celgene ("Natco's Notice Letter"). Natco's Notice Letter alleged that the claims of the '517, '501, '720, '554, '976, '977, '784, '106 and '800 patents are invalid, unenforceable, and/or will not be infringed by the activities described in Natco's ANDA. Natco's Notice Letter also informed Celgene that Natco seeks approval to market Natco's Proposed Products before the '517, '501, '720, '554, '976, '977, '784, '106 and '800 patents expire.

23. In its Notification Letter, Natco offered to provide access to certain confidential information and materials within Natco's ANDA that would allow Celgene to confirm Natco's infringement of the patents-in-suit. The parties did not reach agreement on the terms of such confidential access. To date, Natco has not provided any portion of its ANDA to counsel for Celgene.

24. On information and belief, Natco has entered into an agreement with Natco's Unknown Partner, under which Natco's Unknown Partner will market and distribute Natco's

Proposed Products upon FDA approval of Natco's ANDA throughout the United States, including within the State of New Jersey.

Count I: Infringement of the '517 Patent

25. Plaintiff repeats and realleges the allegations of paragraphs 1-24 as though fully set forth herein.

26. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules, prior to the expiration of the '517 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

27. There is a justiciable controversy between the parties hereto as to the infringement of the '517 patent.

28. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will infringe the '517 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States.

29. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will induce infringement of the '517 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Natco will intentionally encourage acts of direct infringement with knowledge of the '517 patent and knowledge that its acts are encouraging infringement.

30. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will contributorily infringe the '517 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, Natco has had and continues to have knowledge that Natco's Proposed

Products are especially adapted for a use that infringes the '517 patent and that there is no substantial non-infringing use for Natco's Proposed Products.

31. Celgene will be substantially and irreparably damaged and harmed if Natco's infringement of the '517 patent is not enjoined.

32. Celgene does not have an adequate remedy at law.

33. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '501 Patent

34. Plaintiff repeats and realleges the allegations of paragraphs 1-33 as though fully set forth herein.

35. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules, prior to the expiration of the '501 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

36. There is a justiciable controversy between the parties hereto as to the infringement of the '501 patent.

37. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will infringe the '501 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States.

38. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will induce infringement of the '501 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Natco will intentionally

encourage acts of direct infringement with knowledge of the '501 patent and knowledge that its acts are encouraging infringement.

39. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will contributorily infringe the '501 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, Natco has had and continues to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '501 patent and that there is no substantial non-infringing use for Natco's Proposed Products.

40. Celgene will be substantially and irreparably damaged and harmed if Natco's infringement of the '501 patent is not enjoined.

41. Celgene does not have an adequate remedy at law.

42. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement of the '230 Patent

43. Plaintiff repeats and realleges the allegations of paragraphs 1-42 as though fully set forth herein.

44. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules, prior to the expiration of the '230 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

45. There is a justiciable controversy between the parties hereto as to the infringement of the '230 patent.

46. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will infringe the '230 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States.

47. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will induce infringement of the '230 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Natco will intentionally encourage acts of direct infringement with knowledge of the '230 patent and knowledge that its acts are encouraging infringement.

48. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will contributorily infringe the '230 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, Natco has had and continues to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '230 patent and that there is no substantial non-infringing use for Natco's Proposed Products.

49. Celgene will be substantially and irreparably damaged and harmed if Natco's infringement of the '230 patent is not enjoined.

50. Celgene does not have an adequate remedy at law.

51. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '720 Patent

52. Plaintiff repeats and realleges the allegations of paragraphs 1-51 as though fully set forth herein.

53. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules, prior to the expiration of the '720 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

54. There is a justiciable controversy between the parties hereto as to the infringement of the '720 patent.

55. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will infringe the '720 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States.

56. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will induce infringement of the '720 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Natco will intentionally encourage acts of direct infringement with knowledge of the '720 patent and knowledge that its acts are encouraging infringement.

57. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will contributorily infringe the '720 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, Natco has had and continues to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '720 patent and that there is no substantial non-infringing use for Natco's Proposed Products.

58. Celgene will be substantially and irreparably damaged and harmed if Natco's infringement of the '720 patent is not enjoined.

59. Celgene does not have an adequate remedy at law.

60. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count V: Infringement of the '554 Patent

61. Plaintiff repeats and realleges the allegations of paragraphs 1-60 as though fully set forth herein.

62. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules, prior to the expiration of the '554 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

63. There is a justiciable controversy between the parties hereto as to the infringement of the '554 patent.

64. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will infringe the '554 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States.

65. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will induce infringement of the '554 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Natco will intentionally encourage acts of direct infringement with knowledge of the '554 patent and knowledge that its acts are encouraging infringement.

66. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will contributorily infringe the '554 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On

information and belief, Natco has had and continues to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '554 patent and that there is no substantial non-infringing use for Natco's Proposed Products.

67. Celgene will be substantially and irreparably damaged and harmed if Natco's infringement of the '554 patent is not enjoined.

68. Celgene does not have an adequate remedy at law.

69. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VI: Infringement of the '976 Patent

70. Plaintiff repeats and realleges the allegations of paragraphs 1-69 as though fully set forth herein.

71. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules, prior to the expiration of the '976 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

72. There is a justiciable controversy between the parties hereto as to the infringement of the '976 patent.

73. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will infringe the '976 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States.

74. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will induce infringement of the '976 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Natco will intentionally

encourage acts of direct infringement with knowledge of the '976 patent and knowledge that its acts are encouraging infringement.

75. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will contributorily infringe the '976 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, Natco has had and continues to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '976 patent and that there is no substantial non-infringing use for Natco's Proposed Products.

76. Celgene will be substantially and irreparably damaged and harmed if Natco's infringement of the '976 patent is not enjoined.

77. Celgene does not have an adequate remedy at law.

78. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VII: Infringement of the '977 Patent

79. Plaintiff repeats and realleges the allegations of paragraphs 1-78 as though fully set forth herein.

80. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules, prior to the expiration of the '977 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

81. There is a justiciable controversy between the parties hereto as to the infringement of the '977 patent.

82. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will infringe the '977 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States.

83. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will induce infringement of the '977 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Natco will intentionally encourage acts of direct infringement with knowledge of the '977 patent and knowledge that its acts are encouraging infringement.

84. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will contributorily infringe the '977 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, Natco has had and continues to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '977 patent and that there is no substantial non-infringing use for Natco's Proposed Products.

85. Celgene will be substantially and irreparably damaged and harmed if Natco's infringement of the '977 patent is not enjoined.

86. Celgene does not have an adequate remedy at law.

87. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VIII: Infringement of the '784 Patent

88. Plaintiff repeats and realleges the allegations of paragraphs 1-87 as though fully set forth herein.

89. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules, prior to the expiration of the '784 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

90. There is a justiciable controversy between the parties hereto as to the infringement of the '784 patent.

91. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will infringe the '784 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States.

92. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will induce infringement of the '784 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Natco will intentionally encourage acts of direct infringement with knowledge of the '784 patent and knowledge that its acts are encouraging infringement.

93. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will contributorily infringe the '784 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, Natco has had and continues to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '784 patent and that there is no substantial non-infringing use for Natco's Proposed Products.

94. Celgene will be substantially and irreparably damaged and harmed if Natco's infringement of the '784 patent is not enjoined.

95. Celgene does not have an adequate remedy at law.

96. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IX: Infringement of the '106 Patent

97. Plaintiff repeats and realleges the allegations of paragraphs 1-96 as though fully set forth herein.

98. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules, prior to the expiration of the '106 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

99. There is a justiciable controversy between the parties hereto as to the infringement of the '106 patent.

100. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will infringe the '106 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States.

101. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will induce infringement of the '106 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Natco will intentionally encourage acts of direct infringement with knowledge of the '106 patent and knowledge that its acts are encouraging infringement.

102. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will contributorily infringe the '106 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On

information and belief, Natco has had and continues to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '106 patent and that there is no substantial non-infringing use for Natco's Proposed Products.

103. Celgene will be substantially and irreparably damaged and harmed if Natco's infringement of the '106 patent is not enjoined.

104. Celgene does not have an adequate remedy at law.

105. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count X: Infringement of the '800 Patent

106. Plaintiff repeats and realleges the allegations of paragraphs 1-105 as though fully set forth herein.

107. Natco's submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of lenalidomide capsules, prior to the expiration of the '800 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

108. There is a justiciable controversy between the parties hereto as to the infringement of the '800 patent.

109. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will infringe the '800 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States.

110. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will induce infringement of the '800 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, upon FDA approval of Natco's ANDA, Natco will intentionally

encourage acts of direct infringement with knowledge of the '800 patent and knowledge that its acts are encouraging infringement.

111. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco will contributorily infringe the '800 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, Natco has had and continues to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '800 patent and that there is no substantial non-infringing use for Natco's Proposed Products.

112. Celgene will be substantially and irreparably damaged and harmed if Natco's infringement of the '800 patent is not enjoined.

113. Celgene does not have an adequate remedy at law.

114. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XI: Infringement by Natco's Unknown Partner

115. Plaintiff repeats and realleges the allegations of paragraphs 1-114 as though fully set forth herein.

116. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco's Unknown Partner will infringe the '517, '501, '230, '720, '554, '976, '977, '784, '106 and '800 patents under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States.

117. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco's Unknown Partner will induce infringement of the '517, '501, '230, '720, '554, '976, '977, '784, '106 and '800 patents under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and

belief, upon FDA approval of Natco's ANDA, Natco's Unknown Partner will intentionally encourage acts of direct infringement with knowledge of the '517, '501, '230, '720, '554, '976, '977, '784, '106 and '800 patents and knowledge that its acts are encouraging infringement.

118. Unless enjoined by this Court, upon FDA approval of Natco's ANDA, Natco's Unknown Partner will contributorily infringe the '517, '501, '230, '720, '554, '976, '977, '784, '106 and '800 patents under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Natco's Proposed Products in the United States. On information and belief, Natco's Unknown Partner has had and continues to have knowledge that Natco's Proposed Products are especially adapted for a use that infringes the '517, '501, '230, '720, '554, '976, '977, '784, '106 and '800 patents and that there is no substantial non-infringing use for Natco's Proposed Products.

119. Celgene will be substantially and irreparably damaged and harmed if Natco's Unknown Partner's infringement of the '517, '501, '230, '720, '554, '976, '977, '784, '106 and '800 patents is not enjoined.

120. Celgene does not have an adequate remedy at law.

121. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Celgene respectfully requests the following relief:

(A) A Judgment be entered that Natco has infringed the '517, '501, '230, '720, '554, '976, '977, '784, '106 and '800 patents by submitting ANDA No. 201-452;

(B) A Judgment be entered that Natco has infringed, and that Natco's making, using, selling, offering to sell, or importing Natco's Proposed Products will infringe one or more claims of the '517, '501, '230, '720, '554, '976, '977, '784, '106 and '800 patents;

(C) An Order that the effective date of FDA approval of ANDA No. 201-452 be a date which is not earlier than the later of the expiration of the ’517, ’501, ’230, ’720, ’554, ’976, ’977, ’784, ’106 and ’800 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Natco and its officers, agents, attorneys and employees, and those acting in privity or concert with them, including Natco’s Unknown Partner, from making, using, selling, offering to sell, or importing Natco’s Proposed Products until after the expiration of the ’517, ’501, ’230, ’720, ’554, ’976, ’977, ’784, ’106 and ’800 patents, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Natco, its officers, agents, attorneys and employees, and those acting in privity or concert with them, including Natco’s Unknown Partner, from practicing any compounds, methods or compositions as claimed in the ’517, ’501, ’230, ’720, ’554, ’976, ’977, ’784, ’106 and ’800 patents, or from actively inducing or contributing to the infringement of any claim of any of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(F) A Declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Natco’s Proposed Products will directly infringe, induce and/or contribute to infringement of the ’517, ’501, ’230, ’720, ’554, ’976, ’977, ’784, ’106 and ’800 patents;

(G) To the extent that Natco has committed any acts with respect to the compounds, methods or compositions claimed in the ’517, ’501, ’230, ’720, ’554, ’976, ’977, ’784, ’106 and

'800 patents, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiff be awarded damages for such acts;

(H) If Natco engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Natco's Proposed Products prior to the expiration of the '517, '501, '230, '720, '554, '976, '977, '784, '106 and '800 patents, a Judgment awarding damages to Plaintiff resulting from such infringement, together with interest;

(I) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(J) Costs and expenses in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: October 8, 2010

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

I hereby certify that the matter in controversy involves the same plaintiff and five of the same patents (United States Patent Nos. 6,045,501, 6,315,720, 6,561,976, 6,561,977, 6,755,784) that were at issue in the matter captioned *Celgene Corporation v. Barr Laboratories, Inc., et al.*, Civil Action No. 07-286 (SDW)(MCA), which was recently dismissed without prejudice by the Hon. Susan D. Wigenton, U.S.D.J. on May 26, 2010.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: October 8, 2010

By: s/ Charles M. Lizza

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